## Food and Drug Administration, HHS

- (2) Limitations. As in paragraph (d)(5)(i)(A)(2) of this section.
- (ii) Growing Turkeys—(A) Amount. 400 mg/gal, for 7 to 14 days.
- (1) Indications for use. Control of infectious synovitis caused by Mycoplasma synoviae susceptible to chlortetracycline.
- (2) Limitations. Prepare fresh solution daily; use as the sole source of chlortetracycline; do not use for more than 14 consecutive days; do not administer to growing turkeys within 24 hours of slaughter.
- (B) *Amount*. 25 mg/lb body weight daily, for 7 to 14 days.
- (1) Indications for use. Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to chlortetracycline.
- (2) Limitations. As in paragraph (d)(5)(ii)(A)(2) of this section.
- (iii) Swine—(A) Amount. 10 mg/lb body weight daily, for 3 to 5 days.
- (B) Indications for use. Control and treatment of bacterial enteritis (scours) caused by E. coli and Salmonella spp., and bacterial pneumonia associated with Pasteurella spp., A. pleuropneumoniae, and Klebsiella spp. susceptible to chlortetracycline.
- (C) *Limitations*. Prepare fresh solution daily; use as the sole source of chlortetracycline; do not use for more than 5 days; do not administer to swine within 24 hours of slaughter.
- (iv) Calves, beef cattle, and nonlactating dairy cattle—(A) Amount. 10 mg/lb body weight daily in divided doses, for 3 to 5 days.
- (B) Indications for use. Control and treatment of bacterial enteritis (scours) caused by Escherichia coli and Salmonella spp., and bacterial pneumonia associated with Pasteurella spp., Histophilus spp., and Klebsiella spp. susceptible to chlortetracycline.
- (C) Limitations. Prepare fresh solution daily; use as a drench; use as the sole source of chlortetracycline; do not use for more than 5 days; do not administer to cattle within 24 hours of slaughter; do not use in lactating dairy cattle; do not administer this product with milk or milk replacers; administer 1 hour before or 2 hours after feeding milk or milk replacers; a withdrawal period has not been established in preruminating

calves; do not use in calves to be processed for veal.

[57 FR 37324, Aug. 18, 1992]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §520.445b, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

# § 520.445c Chlortetracycline tablets and boluses.

- (a) *Specifications*. Each tablet/bolus contains 25, 250, or 500 milligrams of chlortetracycline hydrochloride.
- (b) Sponsors. See No. 000010 in §510.600(c) of this chapter for the 250-milligram chlortetracycline hydrochloride bolus; see No. 053501 for the 25-milligram tablet and the 500 milligram bolus.
- (c)  $Related\ tolerances.$  See §556.150 of this chapter.
- (d) National Academy of Sciences/National Research Council NAS/NRC) status. The conditions of use specified in this section were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified in §514.111 of this chapter but may require bioequivalency and safety information.
- (e) Conditions of use. Calves—(1) Amount. One 250 milligram bolus per 50 pounds of body weight twice a day for 3 to 5 days.
- (i) Indications for use. Treatment of bacterial enteritis (scours) caused by Escherichia coli and bacterial pneumonia associated with Pasteurella spp., Klesbsiella spp., and Hemophilus spp.
- (ii) Limitations. Administer bolus directly by mouth or crush and dissolve in milk or water for drenching or bucket feeding; if no improvement is noted after 3 days of treatment, consult a veterinarian; do not use for more than 5 days; do not administer within 24 hours of slaughter.
- (2) Amount. One 25 milligram tablet for each 5 pounds of body weight every 12 hours daily for 3 to 5 days.
- (i) Indications for use. Control and treatment of bacterial enteritis (scours) caused by E. coli and Salmonella spp. and bacterial pneumonia associated with Pasteurella spp., Hemophilus spp., and Klebsiella spp., susceptible to chlortetracycline.

#### § 520.446

- (ii) Limitations. Administer tablet directly by mouth or crush and dissolve in water for drenching; if no improvement is noted after 3 days of treatment, consult a veterinarian; do not use for more than 5 days; when feeding milk or milk replacer, administration 1 hour before or 2 hours after feeding; do not administer within 24 hours of slaughter.
- (3) *Amount*. One 500 milligram bolus per 100 pounds of body weight twice a day for 3 to 5 days.
- (i) Indications for use. Treatment of bacterial enteritis (scours) caused by E. coli and Salmonella spp., and bacterial pneumonia associated with Pasteurella spp., Hemophilus spp., and Klebsiella spp., susceptible to chlortetracycline.
- (ii) Limitations. Administer directly by mouth or crush and dissolve in water for drenching; if no improvement is noted after 3 days of treatment, consult a veterinarian; do not use for more than 5 days; do not administer within 24 hours of slaughter.

[57 FR 37325, Aug. 18, 1992, as amended at 67 FR 78355, Dec. 24, 2002]

# § 520.446 Clindamycin capsules and tablets.

- (a) Specifications—(1) Each capsule contains the equivalent of 25, 75, 150, or 300 milligrams (mg) clindamycin as the hydrochloride salt.
- (2) Each tablet contains the equivalent of 25, 75, or 150 mg clindamycin as the hydrochloride salt.
- (3) Each capsule contains the equivalent of 25, 75, or 150 mg clindamycin as the hydrochloride salt.
- (b) Sponsors. See sponsors in §510.600(c) of this chapter as follows:
- (1) Nos. 000009 and 059130 for use of capsules described in paragraph (a)(1) of this section.
- (2) No. 051311 for use of tablets described in paragraph (a)(2) of this section.
- (3) No. 043806 for use of tablets described in paragraph (a)(3) of this section.
- (c) Conditions of use in dogs—(1) Amount. Wounds, abscesses, and dental infections: 2.5 to 15 mg per pound (/lb) body weight every 12 hours for a maximum of 28 days. Osteomyelitis: 5.0 to 15 mg/lb body weight every 12 hours for a minimum of 28 days.

- (2) Indications for use. For the treatment of skin infections (wounds and abscesses) due to susceptible strains of coagulase-positive staphylococci (Staphulococcus aureus orS. intermedius), deep wounds and abscesses due to susceptible strains of Bacteroides fragilis, Prevotellamelaninogenicus, Fusobacterium necrophorum, and Clostridium perfringens, dental infections due to susceptible strains of S. aureus, B. fragilis, P. melaninogenicus, F. necrophorum, and C. perfringens, and osteomyelitis due to susceptible strains S. aureus, B. fragilis, P. melaninogenicus, F. necrophorum, and C. perfringens.
- (3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

 $[67\ FR\ 54954,\ Aug.\ 27,\ 2002,\ as\ amended\ at\ 68\ FR\ 55824,\ Sept.\ 29,\ 2003;\ 69\ FR\ 32273,\ June\ 9,\ 2004;\ 71\ FR\ 39204,\ July\ 12,\ 2006;\ 73\ FR\ 4077,\ Jan.\ 24,\ 2008]$ 

### §520.447 Clindamycin solution.

- (a) Specifications. Each milliliter of solution contains the equivalent of 25 milligrams (mg) clindamycin as the hydrochloride salt.
- (b) Sponsors. See Nos. 000009, 051311, 058829, and 059130 in 510.600(c) of this chapter.
- (c) Special considerations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- (d) Conditions of use—(1) Dogs—(i) Amount. Wounds, abscesses, and dental infections: 2.5 to 15 mg per pound (/lb) body weight every 12 hours for a maximum of 28 days. Osteomyelitis: 5.0 to 15 mg/lb body weight every 12 hours for a minimum of 28 days.
- (ii) Indications for use. For the treatment of skin infections (wounds and abscesses) due to susceptible strains of coagulase-positive staphylococci (Staphylococcus aureus or S. intermedius), deep wounds and abscesses due to susceptible strains of Bacteroides fragilis, Prevotellamelaninogenicus, Fusobacterium necrophorum, and Clostridium perfringens; dental infections due to susceptible strains of S. aureus, B. fragilis, P. melaninogenicus, F. necrophorum, and C. perfringens; and osteomyelitis due to susceptible strains  $\alpha f$ S aureus, B. fragilis,